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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/537,014

03/06/2006

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P70598US0

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EXAMINER

TREYGER, ILYA Y

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

04/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/537,014 | Applicant(s) TANGHOJ, ALLAN | |
| | Examiner ILYA Y. TREYGER | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-23 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/05/2007; 07/31/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant amended claims 1, 19, and 21.
2. Claim 3 is canceled.
3. Claims 1, 2, 4-21, and new claims 22 and 23 of US Application 10/517014, filed 11/28/2003 are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

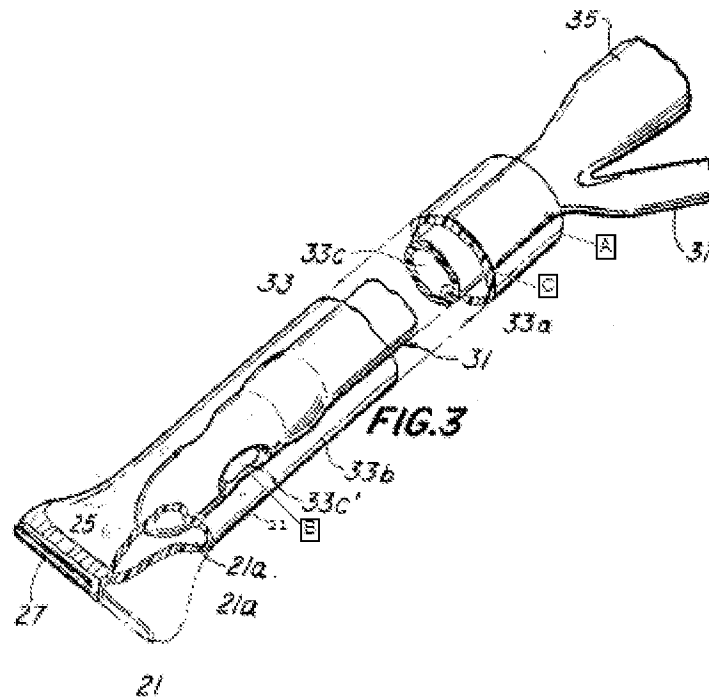
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4-7, 10, 11, 14, 16, 17-19, 21, and 23 are rejected under 35 U.S.C. 102 (b) as being anticipated by Juster et al. (US 3,934,721).
6. In Re claim 1, Juster discloses a catheter with a conduit for draining body fluid from at least one inlet opening B (Fig. 3) in the proximal, insertable, end of the catheter to at least one outlet opening, said catheter comprising first 31 (Fig. 3) and second 35 (Fig. 3) parts, wherein the first part forms the proximal end, and the second part forms the distal end, the first and second parts having different cross- sectional size and/or shape and being joined in a fixed connection, and the first part is at least partly encapsulated in a tube sheath (sleeve) 21 (Fig. 3) to leave at least a portion 35 (Fig. 3) of the second part of the catheter uncovered by the sleeve, said sleeve 21 (Fig. 3) being attached to the catheter with a seal that forms a liquid and/or bacteria tight

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barrier to maintain sterility of at least the encapsulated portion of said first part. (See Col. 1, ln. 65-68; Col. 2, ln. 13-15; Fig. 3).



Since the tube sheath 21 is formed of elastic material capable of self-retaining and restoring its own cylindrical form (Col. 2, ln. 28-32) it is interpreted as a sleeve and the sleeve is frictionally attached to the shaft (Col. 4, ln. 65-69), which means it is sealed.

7. In Re claim 2, Juster discloses the catheter, wherein the sleeve is detachably attached to the outer surface of the catheter (See Fig. 3).

8. In Re claim 4, Juster discloses the catheter, wherein the first part is entirely encapsulated by the sleeve 21 (See Fig. 3).

9. In Re claims 5 and 7, Juster discloses the catheter, wherein the at least one inlet opening B (Fig. 3) is sealed by a detachable closure 21 (Fig. 3).

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10. In Re claim 6, Juster discloses the catheter, wherein the closure forms part of the sleeve (See Fig. 3, c. 27).

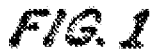
11. In Re claim 10, Juster discloses the catheter, wherein the first 31 and second 35 parts are made in one piece (Fig. 3).

12. In Re claim 11, Juster discloses the catheter, wherein the second part is made with a higher bending moment than the first part (See Fig. 3).

11. In Re claim 14, Juster discloses the catheter, wherein the second part includes a connecting element for connection to a receptacle for collection of the body fluid (See Col. 2, ln. 13-15; Fig. 3, c. 35, 37).

12. In Re claim 16, Juster discloses the catheter, wherein the sleeve is made from a dimensionally stable material (See Col. 2, ln. 25-26).

13. In Re claim 17, Juster discloses the catheter, wherein the sleeve forms part of a package for encapsulation of the first and the second parts in individual compartments (See Fig. 1).



16. In Re claim 21, Juster discloses a sleeve for a catheter with inlet openings in its insertable end, said sleeve comprising an oblong body with a cavity for sealingly enclosing at least a part of the catheter and an opening for inserting the catheter into the cavity, said cavity forming a cap portion covering the inlet openings of the catheter when the catheter is arranged in the cavity,

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said sleeve including a seal member opposite said cap portion that sealingly secures said sleeve to said catheter to form a liquid and/or bacteria tight barrier therebetween. (See Col. 1, ln. 65; Col. 2, ln. 60-62; Fig. 1 and 2).

Since the tube sheath 21 is formed of elastic material capable to self-retain and restore its own cylindrical form (Col. 2, ln. 28-32) the sleeve is fully capable of sealing the connection with the catheter on the distal end A (Fig. 3) of the sleeve 21, and consequently provides liquid and/or bacteria tight barrier. Therefore the distal end A (Fig. 3) of the sleeve 21 has been interpreted as a seal member opposite the cap portion.

17. In Re claim 23, Juster discloses a catheter with a conduit for draining body fluid from at least one inlet opening B (Fig. 3) in a proximal, insertable, end of the catheter to at least one outlet opening, said catheter comprising a first 31 (Fig. 3) part forming the proximal end and a second 35 (Fig. 3) part forming the distal end, the first and second parts being linearly arranged and joined in a fixed connection, said catheter in a storage configuration having the first part at least partly encapsulated in a tube sheath (sleeve) 21 (Fig. 3) to leave at least a portion 35 (Fig. 3) of the second part of the catheter uncovered by the sleeve, said sleeve 21 (Fig. 3) being attached to the catheter in said storage configuration with a seal that forms a liquid and/or bacteria tight barrier between the sleeve and the catheter where attached to one another to maintain sterility of at least the encapsulated portion of said first part while said uncovered portion of the second catheter part remains exposed for handling thereof (See Col. 1, ln. 65-68; Col. 2, ln. 13-15; Fig. 3).

Since the tube sheath 21 is formed of elastic material capable to self-retain and restore its own cylindrical form (Col. 2, ln. 28-32) the sleeve also is fully capable of sealing the connection

with the catheter on the distal end A (Fig. 3) of the sleeve 21, and consequently provides liquid and/or bacteria tight barrier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juster et al. (US 3,934,721).

20. In Re claim 9, Juster discloses the claimed invention except for a particular parameter of length ratio between first and second parts of the catheter.

The length ratio between first and second parts of the catheter depends of the character of manipulations desired and material parts of the catheter are made of, and therefore is the matter of optimization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to elect the length ratio between first and second parts of the catheter depending of manipulation desired and material parts of catheter are made of, since it only involves routine skills in the art.

21. In Re claim 12, Juster discloses the claimed invention except for a catheter, wherein the second part is made with a higher surface friction than the first part.

Difference in surface friction of the catheter parts depends of the character of manipulations desired and material parts of the catheter are made of, and therefore is the matter of optimization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the surface friction of the catheter parts depending of manipulation desired and material parts of catheter are made of.

22. In Re claim 13, Juster discloses the claimed invention except for a particular parameter of the radial size ratio between parts of the catheter.

The radial size ratio between parts of the catheter depends of the character of manipulations desired and material parts of the catheter are made of, and therefore is the matter of optimization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to elect the radial size ratio between parts

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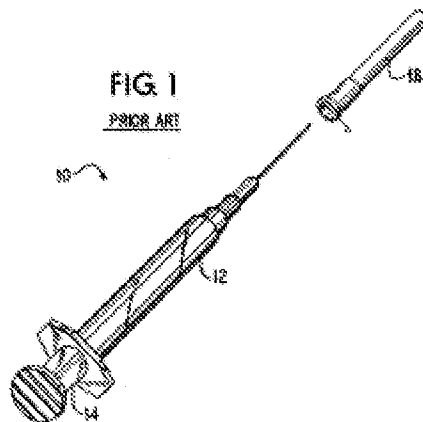
of the catheter depending of manipulation desired and material parts of the catheter are made of.

23. Claims 8 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juster et al. (US 3,934,721) in view of D' Amico (US 5,429,613).

24. In Re claims 8, Juster discloses the claimed invention discussed above, but does not expressly disclose the catheter wherein the first and second parts are made from different materials.

D'Amico teaches an invasion device, wherein the first and second parts are made from different materials (See Fig. 1), since needle made of metal and cylinder made of plastic.

Please note that injection assembly and catheter both belong to invasion devices.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Juster with the first and second parts are made from different materials, as taught by D'Amico, because such modification would improve the manipulation features of the device.

25. In Re claim 22, Juster discloses the claimed invention discussed above, but does not expressly disclose the catheter wherein the seal member is a radially inwardly directed flange that engages with a complementary structure on said catheter to removably lock said sleeve in position on said catheter.

D'Amico teaches the invasion device, wherein the seal member A is a radially inwardly directed flange that engages with a complementary structure on said device to removably lock the sleeve 18 in position on said device (See Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Juster with the seal member A is a radially inwardly directed flange that engages with a complementary structure on said device to removably lock the sleeve in position on said device, as taught by D'Amico, because such modification would convenience the operation of the device.

26. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Juster et al. (US 3,934,721) in view of Starke et al. (US 5,147,341).

27. In Re claim 15, Juster discloses a catheter discussed above, but does not expressly disclose a catheter, wherein the outlet opening is in fluid connection with a receptacle for collection of the body fluid.

Starke teaches that it is known the outlet opening is in fluid connection with a receptacle for collection of the body fluid (See Col. 2, ln. 51-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a catheter of Juster with the outlet opening is in fluid connection

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with a receptacle for collection of the body fluid, as taught by Starke because such modification would provide a urine collection.

28. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robert W. Juster et al. (US 3,934,721) in view of Yeongchi Wu et al. (US 4,204,527).

Juster discloses a catheter discussed above, but does not expressly disclose a catheter made for draining urine from a bladder or urinary tract.

Wu teaches that it is known to use a catheter made for draining urine from a bladder or urinary tract (See Abstract, ln. 4-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a catheter of Juster with a catheter made for draining urine from a bladder or urinary tract, as taught by Wu because such modification would provide draining urine from a bladder or urinary tract.

Response to Arguments

29. Applicant's arguments filed 12/08/2007 have been fully considered but they are not persuasive. Applicant argues that the sheath in Juster is not attached to the catheter and certainly is not sealed thereto so as to form a liquid and/or bacteria tight barrier.

However the tube sheath 21, which is interpreted as a sleeve, is formed of elastic material capable of self-retaining and restoring its own cylindrical form (Col. 2, ln. 28-32), and the sleeve is frictionally attached to the shaft (Col. 4, ln. 65-69), which means it is sealed. Therefore, since

the structural limitations are met by Juster, the sheath of Juster is fully capable of protecting the sterility or being a liquid tight.

30. Applicant further argues that no portion of the outer package 13 of Juster is attached to the catheter.

However since the sleeve 21 is disposed within the outer package 13, it is a part of the package, and thus meets the limitations of claim 17.

Applicant argues that the outer package cannot be interpreted as a sleeve.

It is noted that the Examiner has never interpreted the outer package as a sleeve.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ilya Treyger
Examiner
AU 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761